

# Efforts to make protective medical gear in US falling flat

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When the coronavirus pandemic first hit the U.S., sales of window coverings at Halcyon Shades quickly went dark. So the suburban St. Louis business did what hundreds of other small manufacturers did: It

pivoted to make protective supplies, with help from an \$870,000 government grant.

But things haven't worked out as planned. The company quit making face shields because it wasn't profitable. It still hasn't sold a single N95 mask because of struggles to get equipment, materials and regulatory approval.

"So far, it has been a net drain of funds and resources and energy," Halcyon Shades owner Jim Schmersahl said.

Many companies that began producing [personal protective equipment](#) with patriotic optimism have scaled back, shut down or given up, according to an Associated Press analysis based on numerous interviews with manufacturers. Some already have sold equipment they bought with state government grants.

As COVID-19 was stressing hospitals and shuttering businesses in 2020, elected officials touted the need to boost U.S. production of protective gear. Yet many manufacturers who answered the call have faced logistical hurdles, regulatory rejections, slumping demand and fierce competition from foreign suppliers. After the initial scramble for PPE subsided, many industry newcomers had difficulty selling products.

"At the end of the day, when everybody said they wanted American-made, nobody's buying, not even the state," said Tony Blogumas, vice president of Green Resources Consulting, a rural Missouri firm that received an \$800,000 state grant but has sold only a few thousand masks. "We're kind of upset about the whole situation."

Missouri Gov. Mike Parson also is disappointed. His administration divided \$20 million in federal COVID-19 relief funds among 48 businesses for the production of masks, gowns, sanitizer and other

supplies. Parson hoped to seed a permanent field of manufacturers.

"I'm still a firm believer in that—that we need to be making PPE here in this state," Parson said. "Unfortunately, a lot of entities went right back to where they were getting it before."

The onset of the pandemic revealed that the U.S. was highly dependent on foreign countries for protective gear. When China limited exports because of its own battle against COVID-19, U.S. stockpiles plummeted. Prices skyrocketed as [federal officials](#), governors and health care systems competed for supplies.

Though federal stockpiles have been replenished, shriveling domestic production has raised concerns that state governments, [medical facilities](#) and others could again get stuck scrambling for gear during a future pandemic.

The AP identified more than \$125 million in grants to spur production of pandemic supplies made to over 300 business in 10 states—Alabama, Hawaii, Indiana, Kansas, Louisiana, Maryland, Massachusetts, Missouri, New York and Ohio. It's possible that grants were awarded in additional states, but there is no central clearinghouse to track them.

In November 2020, Alabama awarded one of the single largest grants—nearly \$10.6 million from federal pandemic relief funds—to HomTex Inc. The company was to equip a new Selma facility to make 250 million surgical masks and 45 million N95 masks annually. The plant has yet to make anything due to a lack of customers.

"I can't produce product that I can't sell," HomTex President Jeremy Wootten said.

Some PPE manufacturers point to federal regulations as part of the

reason for their struggles. Three-ply masks need FDA approval to be marketed for medical use—an important designation for building a long-term customer base. Companies need approval from the National Institute for Occupational Safety and Health to market products as N95 respirators, which filter at least 95% of airborne particles.

During the first two years of the pandemic, NIOSH approved 30 new manufacturers—more than seven times the typical number during a similar pre-pandemic period, according to agency data. Some applications remain pending, while numerous others were denied.

Halcyon Shades' N95 certification was rejected in October because its samples didn't have head straps attached. While the company works on another application, its equipment sits idle, with partially finished masks paused on a [conveyor belt](#).

Without federal approval, "we're just dead in the water," said Schmersahl, the company owner.

Progress reports filed with the Missouri Department of Economic Development show that nearly all its PPE grant recipients faced challenges by July 2021, especially with sales.

Ohio awarded \$20.8 million to 73 businesses to manufacture pandemic-related supplies, according to state data. Of 60 businesses that complied with a recent reporting deadline, more than one-third no longer produced PPE by the end of 2021.

Dozens of businesses banded together to form the American Mask Manufacturer's Association with the goal of sustaining the industry. But the group's membership has dwindled as more and more go out of business.

Association organizers say the industry has reached a critical point. They want the federal government to treat PPE manufacturers like the nation's defense industry—entering into long-term contracts to perpetually replenish a stockpile for future pandemics or emergencies.

"If the federal government doesn't come in and help support the U.S. manufacturing base, it's almost certainly going to go back to China, and we'll be just as vulnerable as we were in early 2020 and 2019," said Brent Dillie, the association chairman and co-founder of Premium-PPE, a Virginia manufacturer started during the pandemic that has shed about two-thirds of its roughly 300 employees.

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